



July 20, 2012

VIA ECF

Hon. Tonianne J. Bongiovanni, U.S.M.J.
U.S. District Court for the District of New Jersey
Clarkson S. Fisher Building & U.S. Courthouse
402 East State Street
Trenton, New Jersey 08608

Re: Takeda Pharmaceutical Company Limited, et al. v. Mylan Inc. et al.
Civil Action No. 3:11-cv-02506-JAP-TJB

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Dear Judge Bongiovanni:

We, along with Hogan Lovells, represent Plaintiffs Takeda and Ethypharm¹ in this action; Baker Botts LLP is co-counsel to Ethypharm. We write in response to Mylan's July 13, 2012 letter (D.I. 87) requesting that the Court deny (1) Plaintiffs' request to strike new arguments in Mylan's responsive claim construction submissions and (2) Plaintiffs' request to file a reply claim construction brief and supplemental expert declaration to respond to Mylan's new arguments.² (D.I. 83.) Because Mylan's responsive claim construction brief, along with its expert's 17-page supplemental declaration in support thereof, epitomizes "litigation by ambush," Plaintiffs' requests should be granted.

Mylan's newly-minted claim construction for "enteric coating layer" ('994 patent) is case in point. Until its responsive claim construction brief, Mylan at no point advanced a claim construction for "an enteric coating layer." Mylan only said that term should be given its plain and ordinary meaning and identified no supporting intrinsic or extrinsic evidence (see Joint Claim Construction and Prehearing Statement (D.I. 59)). Even though Plaintiffs disclosed their proposed claim construction for "an enteric coating layer" in accordance with the Local Patent Rules and well in advance of opening briefs, Mylan did not bother to address this term in its opening brief. And yet, for the first time in its responsive brief – with five pages of briefing and 12 paragraphs of supporting expert opinion – Mylan advanced what amounts to a proposed construction for "enteric coating layer" that requires it to be an admixture of an enteric coating agent and sustained-release agent. (Def.'s Br. (D.I. 81) at 14-20; Mumper Supp. Decl. (D.I. 80-3) at ¶¶35-44, 46-47.) Mylan's characterization of its new claim construction for "enteric coating layer" as a mere "clarification" of its plain and ordinary meaning is disingenuous. (Def.'s Ltr. (D.I. 87)

¹ "Plaintiffs" refers to Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals North America, Inc., Takeda Pharmaceuticals LLC, Takeda Pharmaceuticals America, Inc. (collectively, "Takeda"), and Ethypharm, S.A. ("Ethypharm").

² To the extent the Court finds L. Civ. R. 37.1(b)(3) applicable to the parties' dispute, Plaintiffs request that the Court consider this reply.

Hon. Tonianne J. Bongiovanni, U.S.M.J.
July 20, 2012
Page 2

at 2-3.) Mylan's gamesmanship renders the disclosure requirements of the Local Patent Rules meaningless.

Mylan further argues that it was not required to articulate indefiniteness ('632 patent) arguments in its opening brief because it previously disclosed them in its invalidity contentions. (Def.'s Ltr. (D.I. 87) at 3.) Mylan's argument misses the mark. If Mylan intended to address indefiniteness at the claim construction stage, it should have raised substantive arguments in its opening brief so as to allow Plaintiffs adequate opportunity to respond. See *Ed Tobergate Assocs. Co. v. Russell Brands, LLC*, No. 08-2290-JWL, 2009 WL 3756322, at *7 (D. Kan. Nov. 5, 2009) (refusing to consider defendant's indefiniteness argument; finding that plaintiff was not reasonably put on notice where defendant merely indicated in its opening claim construction brief that a term was indefinite but provided indefiniteness arguments for the first time in its responsive brief). It follows that, if Mylan genuinely intended to reserve indefiniteness for summary judgment, it should have refrained from fleshing out its indefiniteness arguments – along with its expert's supplemental declaration in support thereof – in its responsive submissions. (Indeed, it is worth noting that Mylan did not indicate in the Joint Claim Construction and Prehearing Statement that its expert would be opining on indefiniteness.) Accordingly, Mylan's indefiniteness arguments in its responsive submissions should be stricken.

Mylan also asserts that its argument based on the '994 file history that the "enteric coating agent" and "sustained-release agent" must be "separate and distinct" is not new because it previously identified the underlying evidentiary support for that argument. (Def.'s Ltr. (D.I. 87) at 5, citing to Joint Claim Construction and Prehearing Statement.) But the bone of contention is the fact that Mylan waited until its responsive claim construction brief to articulate this argument. Just as with its "enteric coating layer" and indefiniteness arguments, Mylan ambushed Plaintiffs with a new argument without adequate notice.

Mylan further takes issue with one page of Takeda's reply brief that addresses Mylan's blatant mischaracterization of Takeda's expert's deposition testimony in relation to a 10% standard of error for "average particle size." (D.I. 83-1 at 11.) Just as it handled Takeda's expert's testimony in relation to "enteric coating layer" (by completely ignoring unambiguous expert testimony making clear that the term is not limited to an admixture, see D.I. 83-1 at 4), Mylan butchers Takeda's expert's testimony in relation to "average particle size" in its responsive submissions. Takeda is merely setting the record straight.

For the above reasons, Plaintiffs submit that the Court should grant Plaintiffs' request to strike the new arguments from Mylan's responsive claim construction submissions, or in the alternative, permit Plaintiffs to file a reply brief and supplemental expert declaration to rebut Mylan's new arguments.

Hon. Tonianne J. Bongiovanni, U.S.M.J.
July 20, 2012
Page 3

If the Court wishes to discuss the matters raised above in a teleconference,
Plaintiffs are available at the Court's convenience.

Respectfully,

s/John E. Flaherty

John E. Flaherty

cc: Counsel of Record (via email)